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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,820	12/01/2003	Mark Purdie	06275-246001	3603

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BOSTON, MA 02110

EXAMINER

NWAONICHA, CHUKWUMA O

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/725,820	Applicant(s) PURDIE, MARK	
	Examiner Chukwuma O. Nwaonicha	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Current Status

Claims 12-18 and 20-23 are pending in the application.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Specification

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

Title of the Invention

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 13, 16-18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Davission et al., {Phosphorylation of Isoprenoid Alcohols, J. Org. Chem., 1986, 51, 4768-4779}.

Davission et al., disclose applicants claimed salt of methylene bisphosphonic acid. See compound on page 4773, first column; tris(tetra-n-butylammonium)Hydrogen methanediphosphonate.

Claims 12, 13, 14, 16-18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lampi et al., {US 5,237,094}.

Lampi et al., disclose applicants claimed sodium salt of methylene bisphosphonic acid. See column 2, example 1.

Claims 12, 13, 14, 16-18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosini et al., {US 4,621,077}.

Rosini et al., disclose applicants claimed sodium and aniline salts of methylene bisphosphonic acid. See column 3, line 26.

Claims 12-18 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchinson et al., {Synthesis of alkylated methylene Bisphosphonate via Organothallium Intermediates, Journal of Organometallic Chemistry 1985, 291 (2), 145-151}.

Hutchinson et al., disclose applicants claimed sodium salt of methylene bisphosphonic acid. See page 147, compound 1e .

Claims 12-18 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Staibano, {EP 0 200 980}.

Staibano discloses applicants claimed sodium salt of dichloromethylene diphosphonic acid. See page 4, lines 2-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

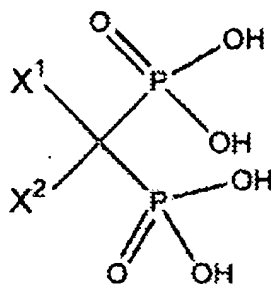
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 12-18 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampi et al., {US 5,237,094}.

Applicants claim a salt of substituted and unsubstituted methylene bisphosphonic acid of the general formula 1;

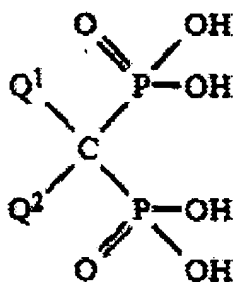


formula I

wherein X¹ and X² are independently, halogen or hydrogen, and all the other variables are as defined in the claim.

Determination of the scope and content of the prior art (M.P.E.P. §2141.01)

Lampi et al. teach the salt of methylene bisphosphonic acid of general formula II;



formula II

wherein Q¹ and Q² are hydrogen or halogen, and the salt of organic and inorganic bases. See column 2, lines 39-44.

Ascertainment of the difference between the prior art and the claims (M.P.E.P., §2141.02)

Lampi et al. salt differs from the instantly claimed salt in that the instantly claimed salt is a more limited genus. However, the scope of the Lampi et al. embraces the genus of the instantly claimed salt.

Finding of prima facie obviousness—rational and motivation (M.P.E.P. §2142-2143)

The instant claimed salts of methylene bisphosphonic acid would therefore have been suggested to one of ordinary skill because one wishing to obtain methylene bisphosphonic acid salt of general formula 1 is taught to select a compound from the genus of Lampi et al.

One of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention by varying the variables of the genus of Lampi et al. to arrive at the instantly claimed salts. Said person would have been motivated to practice the teaching of the reference cited because it demonstrates that the salts of methylene bisphosphonic acid can be obtained. The instant claimed invention would therefore have been obvious to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

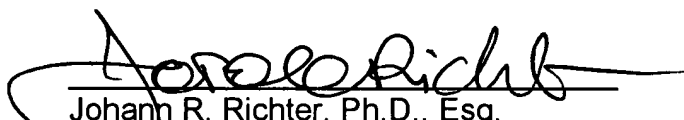
Claims 12-18 and 20-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of prior U.S. 6,657,076. The presently claimed salts of methylene bisphosphonic acid are disclosed in U.S. 6,657,076. See column 7, claim 12 of U.S. 6,657,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlaps substantially with the scope of claim 12 in the U.S. 6,657,076 and differ only that U.S. 6,657,076 is a more limited genus. However, the scope of the instant claims embraces the genus of U.S. 6,657,076. This difference is not a patentable distinction because U.S. 6,657,076 teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1621



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